

Education for the Prevention of Diabetes

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Abstract

Randomized controlled trials and systematic reviews of paired education involving both diet and activity recommendations have shown significant reductions in the advancement of adult (age 18 to 80) prediabetes to type 2 diabetes mellitus (T2DM). Paired education on diet and activity has been effective for persons from diverse races, ethnicities, and levels of education. For this project, the paired education focused on the dietary guidance of the Whole 30 plan and the current exercise/activity recommendations of the American Diabetes Association (ADA). The ADA recommends 30 min 5 x week or 60 min 3 x week of exercise, with no more than 48 hours between exercise occurrences. Ten adults with HbA1C between 5.7%-6.4%, levels specified by the ADA as prediabetes, were invited to participate in the project at an outpatient wellness practice. Participants took a pretest on basic food and activity knowledge, received educational sessions on the Whole 30™ plan and activity recommendations from the ADA, then completed a posttest. Participants were scheduled for one month follow ups. At the 3 month follow up appointment, repeat HbA1C was drawn. Most of the patients (7/10) completed return appointments at the 3-month time frame. Statistically significant results were seen in diet and exercise knowledge using a paired T-test. Clinically significant reductions were seen in HbA1C averages as well as weight, BMI, and glucose levels.

Introduction

The total number of diabetics has increased to over 300 hundred million people worldwide during 2015. This alarming rate is expected to grow to an estimate of greater than 500 million per year by 2035 (Center for Disease Control and Prevention, n.d.). The American Diabetes Association (ADA) estimates that over 3,835 people are diagnosed with diabetes in America each day, which places the annual number of new cases well over one million each year (ADA, n.d.). Additionally, the ADA reports there are 27 million diabetics in the U.S. today and another 86 million individuals at various stages of pre-diabetes. (ADA, n.d.).

Problem Statement

While the ADA's estimates may be at the high end of diabetes diagnoses, these figures do raise concern about a very serious medical problem. In a recent study published in the Journal of American Medical Association (JAMA), it was estimated that 12-14 percent of the United States population has diabetes (Menke, Casagrande, Geiss, & Cowie, 2015). Healthcare costs associated with diabetes have escalated to an alarming rate of 322 billion dollars a year in the United States alone. It is estimated that one out of every five dollars spent on healthcare in the US is spent for the treatment of diabetes (ADA, n.d.). The prevalence of mortality and morbidity associated with type 2 diabetes mellitus (T2DM) continues to cause increased demands on healthcare (Maindal, Toft, Lauritzen, & Sandbaek, 2012). Prevalence of T2DM more than tripled from 1980-2011. This dramatic increase is reflective of the number of individuals classified as overweight or obese as well as an aging population, increased number of minority populations, and enhanced ability for early detection of diabetes and prediabetes (Parker, Byham-Gray, Denmark, & Winkle, 2014). T2DM has reached epidemic levels and is now the leading cause of

new diagnosis/cases of non-traumatic limb amputations and vision impairment including blindness and renal failure in the United States (Morey et al., 2012).

In 1997, the ADA brought forward new diagnostic criteria for identifying individuals at an increased risk for advancement into T2DM. This intermediate stage of diabetes includes two subsets of individuals: those with an impaired fasting glucose, defined as fasting glucose blood samples that measure between 100-125 mg per dl on the 75-g oral glucose tolerance test and those with impaired glucose tolerance, defined as fasting glucose blood samples that measure between 140 – 199 mg. (Kanat, Defronzo, & Abdul-Ghani, 2015). In addition, the ADA and the American Medical Association (AMA) have recommended the use of HbA1C measurements to assist in the diagnosis of pre-diabetic or intermediate stage patients. Currently, the guidelines for utilizing the HbA1c measurement accepted by the ADA and the AMA classify patients with an HbA1C value between 5.7% and 6.4% as pre-diabetic (ADA, n.d.) (Menke et al., 2015). Individuals with impaired glucose tolerance or HbA1C values in prediabetic range have an increased risk of advancement to T2DM.

Over 344 million individual adults worldwide meet the criteria for diagnosis of prediabetes (Cole, Boyer, Spanbauer, Sprague, & Bingham, 2013). Of those, it is estimated that 86 million adults or 37% of the adult population in the United States of America meet the present diagnostic measures for prediabetes (Gopalan et al., 2015).

Purpose and Rationale

It has been widely accepted that prediabetes is a healthcare problem because of the increased likelihood of progression to T2DM. Proactive changes in diet and activity have many positive ramifications; specifically, the reduced risk of heart attack, stroke, vision disturbances and blindness, renal failure, and loss of extremities, all of which are associated with the diagnosis

of T2DM (Perreault et al., 2014). Effective education provided to the pre-diabetic population may have the potential to substantially reduce pre-diabetic patients' HbA1C results to less than 5.7 percent and thereby reduce the risk of advancement to T2DM (Gopalan, Lorincz, Wirtalla, Marcus, & Long, 2015). The overall clinical benefit to patients and the economic benefit mandate efforts to prevent diabetes through intervention (Menke et al., 2015).

There are approximately 86 million pre-diabetic adults aged 20 years and older in the United States population who may not know they are in the early stages of advancement into T2DM (Center for Disease Control and Prevention, n.d.). The risk for advancement into T2DM from the early stage of prediabetes is as high as 70 percent (Block et al., 2015)..Menke et al. (2015) estimated that 12-14% of the U.S. population has diabetes and that 37-38% of the United States population is in the intermediate stages of diabetes. This brings the estimated total to an astounding 49-52%, which indicates approximately one out of two Americans may currently be in a state of prediabetes or diabetes (Menke et al., 2015).

Review of the internal patient data at one private clinic specializing in metabolism showed that 1200 individual patients (out of 4500 charts reviewed) were diagnosed with prediabetes, insulin resistance, impaired fasting glucose, or impaired glucose tolerance. Currently the practice has no structured process for educating newly diagnosed pre-diabetic patients about diabetes prevention beyond the information given at the time of diagnosis. The purpose of this project was to demonstrate the feasibility of implementing an evidence based education intervention on paired diet and activity intended to reduce the risk of advancement from prediabetes to T2DM in the adult population.

Background and Significance

The current standard of care/usual care is not effective in prevention of T2DM in healthcare today. Studies suggest that providing education to adults at the prediabetic level can prevent T2DM. Education on diet and exercise with a focused intervention on lifestyle augmentation assists in improved glucose management and reduction of risk factors associated with T2DM. Reduction in the advancement of prediabetes to T2DM in the adult patient may be successfully accomplished if a focused education intervention on diet, activity, and/or lifestyle modification is integrated into healthcare delivery (Xiao et al., 2015).

Primary disease prevention for individuals in the prediabetic category is rare and not the current standard of care. Usual/current standard of care for individuals who are diagnosed with prediabetes includes brief education delivered at the time of the laboratory results review. Currently, the most common education process begins at the time of T2DM diagnosis or after a patient is categorically classified as having a chronic disease (Kramer, McWilliams, Chen, & Siminerio, 2011). Unfortunately, the time and depth of information needed to adequately address prediabetes cannot typically be managed during a routine office appointment, often leading to a patient's lack of understanding in how to address this healthcare concern. Educational healthcare appointments for further diabetes education are not typically initiated until HbA1C levels exceed 6.4% and most healthcare insurance coverage does not authorize education until a diagnosis of type 2 diabetes has been established.

Advanced practice registered nurses, registered nurses, dietitians, and certified diabetes educators comprise the majority of the current clinical professionals who provide diabetes education (Martin, Warren, & Lipman, 2013). All the above individuals have been accepted as well prepared healthcare professionals experienced in the role of diabetes educator (Martin et al., 2013). In addition, they are healthcare professionals who have achieved a fundamental body of

knowledge and expertise in biology, social sciences, communications, counseling, and education surrounding diabetes (Haas & Maryniuk, 2012). Generally, health care professionals rely on systematic processes to administer diabetic education only after diagnosing type 2 diabetes. The significance of intervention at the prediabetic level by healthcare professionals who have a readily available network of professional and public/community support, is that they can positively contribute in the management and education necessary for diet, activity and lifestyle modification (Kramer, McWilliams, Chen, & Siminerio, 2011). Healthcare professionals utilizing these talents and skill sets fulfill a unique role in dramatically reducing the risk of the pre-diabetic patient advancing to a diagnosis of T2DM (Cole, Boyer, Spanbauer, Sprague, & Bingham, 2013).

PICOT Question

The PICOT question posed to guide the evidence search was, “In pre-diabetic adults, how does incorporating a focused educational intervention on diet, activity, and lifestyle modification compared to the current/usual standard of care affect glucose management and risk factors associated with advancement to T2DM over a three-month period of time?”

Search Strategies

An exhaustive search of the literature included three primary databases CINAHL, PubMed, and Cochrane Review using the keywords (with Boolean connectors) prediabetes (or) prediabetes (and) education (or) diabetes prevention (and) insulin resistance. Searches were restricted to peer-reviewed journal articles written in English and published from 2008 to 2016 with available full text. Abstracts and evaluation tables were examined to determine relevancy to the clinical question. Studies considered for inclusion were required to have diet, activity, or a

combination of both for lifestyle modification as the primary intervention, with prediabetic or diabetes prevention as the primary subjects.

Cochrane

The Cochrane Database was assessed under Cochrane Library, yielding a total of seventy-four articles and three systematic reviews. Two out of the three systematic reviews as well as twelve out of the seventy-four articles were chosen for further appraisal for a synthesis review. The database was searched using the keywords (with Boolean connectors) prediabetes (or) prediabetes (and) education (or) diabetes prevention (and) insulin resistance.

CINAHL

A search in CINAHL produced three hundred and seventy-two articles, and after accounting for redundancies, seven articles from the three hundred and seventy-two were collected for further appraisal and synthesis. The database was searched using the keywords (with Boolean connectors) prediabetes (or) prediabetes (and) education (or) diabetes prevention (and) insulin resistance.

PubMed

Lastly, PubMed yielded 303 articles, of which 14 were selected for further appraisal for a synthesis review. The database was searched using the keywords (with Boolean connectors) prediabetes (or) prediabetes (and) education (or) diabetes prevention (and) insulin resistance. Exclusion criteria in the articles included the following: studies published before 2008, those written in a language other than English, doctoral dissertations, and those with a focus on only one race.

A total of 37 articles were compiled from the databases and 5 additional studies were collected from hand searches.

Critical Appraisal & Synthesis

The research on prediabetes and prevention of advancement to T2DM is extensive. There are a wide variety of recommendations within the research on how to best prevent the advancement of prediabetes to T2DM. The 10 studies chosen for this critical appraisal revolved around the concept of education provided on diet, activity, or both to prediabetics or those at higher risk of advancing to T2DM (Appendix A).

All interventions reviewed were focused on education. Many of the studies, seven in number, concentrated effort in an individual and/or group method of education. One study only used group format, one study only focused on physical activity, and one article only used automated electronic education (Appendix E). These articles were chosen specifically to demonstrate differences in the educational programs spanning from automated education to only activity education to diet and activity education paired together. In addition, group versus individual training was reviewed (Appendix A & E).

Six out of the ten studies chosen were randomized controlled trials, two were systematic reviews, one was a non-randomized 1-group prospective pretest posttest study, and one was a pooled cross-sectional analysis (Appendix A & E). Level of evidence ranged from Levels I to III, indicating strong evidence in the articles (Melnyk & Fineout-Overholt, 2005, Appendix E).

Heterogeneity in the population and demographics was demonstrated with age varying from 18 to 80, a wide variety of race and ethnicities, and several levels of education ranging from high school/GED to postgraduate. In contrast, homogeneity was seen in the independent and dependent variables. Most of the articles utilized similar dependent variables, including fasting blood glucose levels and reduction in risk factors associated with advancement to T2DM (including the most common variables of weight, body mass index, systolic and diastolic blood

pressure, lipid levels, diet management, physical activity, likelihood of engaging in follow up care, and HbA1C levels)(Appendix A & E). The independent variables also demonstrated homogeneity and were concentrated on education provided about diet, activity, or combination of the two in either individual, group, or automated sessions.

Although outcome measurements did demonstrate some heterogeneity, the articles about studies focused on diet paired with activity demonstrated the most statistically significant results in improvement of fasting blood glucose levels as well as additional reduction in risk factors associated with T2DM (Appendix A & E). The study which primarily concentrated on physical activity education failed to show significant results in any category. This article was presented to further outline that the greatest level of response and improvement in glucose management as well as reducing the risk of T2DM was seen when groups or individuals received education about a combination of diet and activity by an individual trained in diabetes education. The articles examined appear to have commonality focused around the benefit of the combination of diet and activity education for prediabetic adults. When either physical activity or diet modification alone was reviewed, the impact on fasting blood glucose levels as well as risk factors associated with advancement of diabetes was not as clinically significant. The research supports prediabetic adults receiving education from healthcare professionals who have advanced understanding of diabetes and diet/activity modification.

For this project the Rosswurm & Larrabee's Model for Evidence-Based Practice Change (Melnik & Fineout-Overholt, 2005) (Appendix F) provided the framework for moving the "idea" of improved prediabetic education and possible risk reduction of advancement of T2DM to a tangible process and viable project for effective implementation and evaluation. Each of the six steps associated with the model were validated in this project. First, in the assessment stage,

the need presented itself in the office practice with increasing numbers of individuals developing prediabetes. Second, in the link stage, the problem of increased number of prediabetes diagnoses can be connected to an education intervention with an outcome of reduced risk of advancement to type 2 diabetes. Third, in the synthesis phase, the evidence was exhaustively reviewed. Fourth, in the design stage, the practice change of a paired diet and activity education method was proposed and expected outcomes were defined as reducing the risk of advancement of the prediabetes to T2DM. Fifth, during the implementation and evaluation stages, the evaluation process determined relative viability of the project in this practice site. Lastly, in the sixth and final stage, if the project warrants a practice change, that will be communicated through practice stakeholders and integrated into a standard of practice (Melnyk & Fineout-Overholt, 2005).

Contribution of Theory

In conjunction with an effective model such as the Rosswurm & Larrabee's Model for Evidence Based Practice Change an equally robust theory was needed to guide the intervention of focused educational intervention on diet, activity, and lifestyle modification. The nursing theory chosen for this project was The Health Promotion Model developed by Nola Pender (Appendix G) (*Health Promotion Model*, 2015). This theory was chosen in relation to evidence based research supporting it as a theory which: is tailored to educational interventions, has merit when dealing with healthcare education topics, and supports the theory that patients will not only endorse the educational process but also make positive changes to enhance their overall wellbeing (Melnyk & Fineout-Overholt, 2005). On further examination, The Health Promotion Model makes the following assumptions when guiding health education interventions. First, individuals look to dynamically control their own actions. Second, biopsychosocial intricacies attempt to work together with their environments. Third, the environment molds the patient over

time. Fourth, Health professionals make up a large part of the relational environment with patient interactions. Lastly, the theory promotes the idea that individuals look to advance and reconfigure their own environments and develop collaboration arrangements which are essential to behavior change.

Project Methods

The protection of human subjects was of paramount importance. The Institutional Review Board (IRB) at Arizona State University approved the study under expedited review on 8/5/2016 (Appendix H). Furthermore, patient's privacy interests were protected by involvement only with providers and staff within Desert Jewel Wellness. Data for the project was retrieved from the participants' existing charts within the practice's password-protected Electronic Medical Record (EMR). De-identified data for analysis was stored on a password-protected laptop until completion of the project. Criteria for inclusion consisted of English speaking adults who could consent.

The setting for the project was a private healthcare practice named Desert Jewel Wellness. In the practice, there is a culture which endorses a nondiscriminatory, open and honest communication, and more holistic approach to healthcare. A wide variety of tools are utilized in the practice, including, but not limited to, one on one education, and metabolic evaluation incorporating imaging, diagnostic bloodwork, and epithelial and DNA testing.

The intervention for the project consisted of diet and activity educational session (Appendix J) combined with a pretest (Appendix K) evaluating knowledge of current evidence based recommendations regarding diet and exercise. The pretest was a 11-question tool focused on food knowledge and current ADA recommendations for activity. The educational intervention was a synthesis The Whole 30™ dietary guide that recommends avoiding specific types of food

for 30 days and then systematic reintroduction of foods. The current ADA recommendations on activity were paired with the dietary recommendations. Participants were asked to complete a basic food and activity quiz to assess their current knowledge at the initial appointment (Appendix K). Additionally, they were provided with summaries and explanations of The Whole 30™ plan (Appendix J) and the current ADA (Appendix J) recommendations on activity and exercise. Patients were then scheduled for a return appointment in 3 months for repeat assessment of their knowledge and quarterly lab results that included HbA1C values as well as glucose levels. Measurements of weight and BMI were collected at each appointment.

Outcomes measured included the 12-week HbA1c result as well as lifestyle modifications including healthy eating and lifestyle habits. Notably, the sensitivity and specificity of the HbA1C test has been established and endorsed by organizations such as the Center for Disease Control (CDC), the American Diabetes Association (ADA), and the American Medical Association (AMA) to register accurate percentages of circulating glucose levels over a 12-week period of time (Haas & Maryniuk, 2012) (Menke, Casagrande, Geiss, & Cowie, 2015) (ADA, n.d.). Initial visits and subsequent visits for the participants were eligible for 3rd-party reimbursement.

Statistical analysis was completed on the following values and measurements: BMI, HbA1C, knowledge assessment quiz, weight, and glucose. Analysis consisted of paired t-test on values pre- and post- intervention. The preintervention data was completed through chart review (glucose, HbA1C) and during initial appointment upon consent to join the project (BMI, weight, knowledge assessment quiz). Post intervention analysis was completed with patients on return appointment through chart review (glucose and HbA1c) and with intake for appointment (BMI, weight and repeat knowledge assessment quiz).

Outcomes & Discussion

Of the 10 individuals who volunteered to participate in the project, 7 completed both the pre and post intervention measures. A mean score for the pretest was 6.7143 and mean posttest value was 10.4286. Utilizing a paired t-test, statistically significant differences were seen with 2-tailed significance value of .001 for pre- and post- knowledge assessment quiz scores. Support for statistical significance with very small sample sizes is reviewed thoroughly in Winter's (2013) review stating that a paired t-test is reasonable with very small subject size if the within-pair correlation is high as we have in this sample of 7 patients for this project. Furthermore, Winter (2013) states that there are no formal objections to using a t-test with a sample size as small as 2. Understandably, the possibility for error in inference is higher with smaller sample sizes.

The mean HbA1C value pre-project intervention was 5.9% and the post project intervention value decreased to 5.7%. This is clinically significant in that the entire range for prediabetes is only .8, so a reduction of .2 percentage points could remove the patient from the risk category associated with prediabetes and T2DM. This clinically significant change only enhances the need for early intervention with prediabetic patients. Effective communication of paired diet and activity with proper screening likely will be a valuable tool to any healthcare provider looking to make a difference in lowering the number of prediabetics advancing to T2DM.

Each of the 7 patients in this project did complete pre and post review with initiation and at 3 months. However, some patients were seen at intervals closer to every 4 weeks. The more frequent patient appointments occurred in relation to patients wishing to have additional follow up appointments to track their individual progress. Additionally, these appointments allowed for

any further questions and/or concerns the patient may have come up with while completing the intervention and allowed for them to be addressed effectively. This additional follow up may have assisted some individuals in their understanding of the concepts surrounding the importance of diet and exercise as it pertains to prediabetes and the risk of advancement to T2DM. In this project, the lead educator was also a certified diabetes educator whose expertise may have supported more effective and engaging education with the project participants. Some benefit comes from having patients who are already established with the practice are familiar with the provider providing the education. Patient “buy in” may be affected if this project were started with new patients who do not already know and respect the healthcare provider: 2 of the 3 individuals who did not follow up for post project review at three months were new patients to the lead educator. Respect within the healthcare community the provider serves in was very beneficial to this project and likely would be an integral part to implementation in any practice. If the project is understood and respected the participation in the project is likely to be enhanced, this again was a benefit in this project in that in office support was high as well as outside provider support.

Conclusion

The culture of healthcare is on the cusp of dramatic change, and after this year’s US elections there have been dramatic changes within the profession of healthcare and to the Affordable Care Act. The project described was based on a goal of assisting individuals in sustaining healthier lifestyles. The ability to effectively engage patients, healthcare providers, and policy makers with proactive management opportunities based in evidence and research will be a crucial role of the future DNP leader. This project is a prime example of how future DNP

leaders can assess a critical healthcare need and effectively synthesize the evidence, design a practice change, implement the plan accordingly, and integrate a sustainable change.

Few barriers or gaps presented themselves through the course of the project. This very likely could have been related to enthusiastic response from patients already established within the practice or from referrals related to the foundation of care the practice had already established within the community. Community support from other healthcare providers, some of who were already patients of the practice, was present and positive feedback was plentiful on review of the project. Return visits were occasionally delayed, but patient reminders proved effective in managing scheduled visits. There was enough interest with new and established patients, as well as referring healthcare providers, that if the project closure deadline had not been reached, the project could have continued for an indeterminate amount of time. These aspects make the project a viable opportunity for other practices to initiate. Sustaining the project within Desert Jewel Wellness would be highly manageable and would cost little more than the reimburseable time and effort of providers to initiate the educational intervention. Medical assistants could easily initiate the pre and post-testing material as well as the needed data to target appropriate patients for education. This would likely hold true in most healthcare offices.

In this project, the director established a successful framework that addresses the innovative techniques of effective evidence based research and treatment in regards to lifestyle modification. Additionally, this project demonstrated innovative ways the Doctor of Nursing Practice can influence and assist in creating realistic and sustainable ways of advancing management of the persons with prediabetes.

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Appendix A

Evaluation Table

Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
<p>Cole, R.E., et al. (2013). Effectiveness of prediabetes nutrition shared medical appointments: Prevention of diabetes.</p> <p>Country: USA</p> <p>Bias: None</p>	<p>Health belief model</p>	<p>Design: RCT.</p> <p>Purpose: Evaluate the effectiveness of a nutritional-based shared medical appointment (SMA) intervention in treatment of prediabetes vs. individual counseling standard of care.</p>	<p>n = 301</p> <p>n, RCT @ 1 yr. = 94.</p> <p>SMA: n=34</p> <p>Control, n=31</p> <p>LTF, n=29</p> <p>Average age: 58.3 ± 9.6.</p> <p>BMI 30.8 ± 4.9.</p> <p>FBG 109±9.5.</p> <p>Males=54%</p> <p>Caucasians= 64%.</p> <p>70% reported exercise.</p> <p>15% met 150min per week recommendation.</p> <p>Inclusion Criteria: Min Age = 18</p> <p>Fluent in English</p> <p>Diagnosis of PreDM (IFG/ FBG=100-125)</p> <p>Completion of 3 hr. prediabetes education class</p> <p>Exclusion Criteria:</p>	<p>ADA standard of Care: FBG>=125</p> <p>HbA1c, <6.5%.</p> <p>BP<=130/80</p> <p>TC = < or =200,</p> <p>LDL < or =100</p> <p>Trigs = 150</p> <p>Exercise e= 150min/wk.</p> <p>IV1= SMA groups and Time (Baseline, 3M, 1yr).</p> <p>IV2= No-SMA</p> <p>DV1: FBG</p> <p>DV2:HbA1C</p> <p>DV3: WT</p> <p>DV4: BMI</p> <p>DV5: BP</p> <p>DV6: CHOL, TC, LDL, HDL, TG.</p>	<p>Primary: FBG mg/dl</p> <p>Secondary: WT w/ electronic scale.</p> <p>BMI calculated kg/m².</p> <p>BP</p> <p>Measured w/ electronic sphygmomanometer.</p> <p>HbA1c: %.</p> <p>Lipid profile</p>	<p>SPSS</p> <p>IV: Paired T-Test of change in primary and secondary from baseline to 1yr.</p> <p>DV: Mean ± SD.</p> <p>1-way analysis of variance with repeated measures for each variable.</p> <p>Statistical significance set at P < .05.</p> <p>Demographic data were reported as frequency and percentage.</p>	<p>SMA Group: Although not to goal of 10mg/dl, FBG 6mg/dl seen within SMA group vs CG.</p> <p>Additionally, SMA vs CG had more wt. loss.</p>	<p>S: SMA work appears to have promise in attempting to increase ability to educate more than one pt. at a time. Further research in SMA work need to be conducted.</p> <p>S: Cost effective time management with CDE through SMA intervention is significant in reduction of FBG.</p> <p>WN: Lacks statistical significance between SMA and CG P: <0.05.</p> <p>WN: Attrition rate.</p> <p>WN: Small size</p> <p>WN: Risk of Type 2 error in suggesting no significance between SMA and CG r/t small sample size.</p> <p>AP: Guidance in determining statistical significance in relation to sample size as well as SS in regards to DVs</p>

Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
			Diagnosis of DM. Did not attend PreDM class prior to RCT. AR: 80% 3 months, 69% year 1					
Gopalan, A., et al. (2015). Awareness of prediabetes and engagement in diabetes risk-reducing behaviors. Country: USA Bias: Cross-sectional data limitations. Recall bias. Social desirability bias.	Health belief model	Design: Pooled Cross-sectional analysis from two consecutive cycles '07-'08 and '09-'10 of the NHANES Purpose: To investigate whether adults with PreDM aware of their diagnosis were more likely to report engaging in diabetes risk-reducing behaviors vs. adults who were unaware of their diagnosis.	2007-2010 NHANES n= 20,686. PreDM n= 2694. PreDM aware n= 288. PreDM unaware n= 2,406 Inclusion criteria: Prediabetic. Exclusion criteria: Age<20 Pregnant Missing/unrealistic HbA1C	IV1: PreDM aware IV 2: PreDM unaware DV1: Phys activity DV2: Wt. mgnt DV3: Combo of both Markers eval: -Age -Gender -Race/ Ethnicity -Education -Income -Insurance status -Places of regular care -Healthcare visits in the last year	DV1: Any physical activity. Moderate activity DPP recom: >150 min/wk. of at least moderate activity DV2: Any weight related behavior BMI appropriate weight related behavior	Chi-square tests and t tests were performed to determine differences between IV1 and IV2. Multivariate logistic regression was run between outcomes. Regression models adjusted for Markers noted.	SS: between IV1 and IV2 in all categories of DV 2 minus "Lost ≥ 7% body wt. in the past year" as well as all categories of DV3. Improvement in all classes but not to level of p , 0.05.	S: SS seen in majority of categories associated with clinical project. S: Long study S: large study. WN: Pt bias WN: Pt recall for many measurements. WN: Social desirability in relation to study outcome. AP: Applicable insight in awareness of prediabetes state as well as education in regards to diet and activity in reducing risk of advancement to DM2.

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			Missing responses to predictor/outcome questions No prediabetes by HbA1C value Self-reported DM Norm glycemic by HbA1C value AR: not stated.	-Family HX of DM -Activity limitations -PHQ-9 score -BMI -Hx of CV disease -# of CV conditions -SBP -DBP -LDL cholesterol -HbA1C	Lost ≥ 7%body wt. in the past year. DV3: Any physical activity + any weight related behavior. At least moderate activity + BMI approp weight behavior. Exercise ≥ 150 min/wk. + 7% wt. loss.	Stata, version 12.1 for Mac was used for data management and analysis.		
Kramer, M.K., et al. (2011). A community-based diabetes prevention program: Evaluation of the group lifestyle balance program delivered by diabetes educators. Country: USA Bias: Project funding provided	Translational Model	Design: 1 group nonrandomized prospective pretest-posttest study design Purpose: To determine if individuals at risk for diabetes who participate in interventions delivered by trained diabetic educators in existing diabetes	N= 121 referrals received N = 95 eligible N= 81 enrolled in program Enrolled per site varied: 44 = rural area, 20 = suburban area, 17 = urban area. M N=10 W N= 71 Inclusion criteria: Nondiabetic individuals at least	IV1: Group Lifestyle Balance (GLP) program. IV2: CG DV1: Wt. loss. DV2: FBG. DV3: LDL, HDL, TG. DV4: Abdominal obesity. DV5: HTN 12 session group lifestyle intervention adapted from DPP lifestyle intervention with the same goals as the	DV1: Wt. without shoes. DV2: Measured 8hr fast. DV3: Local laboratory. DV4: midpoint between lower rib margin and iliac crest repeated x 2.	Mean changes between pre-intervention and post intervention analyzed with t-test when change data was normally distributed. Nonparametric Wilcoxon matched pairs single	Statistically significant positive changes correlated with (p≤.001) in: wt. loss, waist circumference, BMI, total cholesterol, LDL, HDL, TG, HTN.	S: Diabetes educator role enhanced by research. S: Cost of education shown to be low at 275-375per person. WN: no control group non randomized all participants were intended to treat. WN: sample size relatively small. WN: Decreased diversity in regards to population.

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by Sanofi-Aventis US		self-management education community based programs can reduce risk factors for diabetes and cardiovascular disease.	25yrs old with BMI \geq 25kg/m ² who had prediabetes (defined as FBG 100-125) and/or metabolic syndrome per the National Cholesterol Education Program Adult Treatment Panel III definition Exclusion Criteria: Within one yr. with labs confirming: previous DM diagnosis. Women currently or within the last 6 weeks pregnant or lactating. Any person deemed by one's physician as not to be candidate. Any person planning to leave the area before the end of the study.	DPP, including achievement of wt. loss of 7% from starting wt. and increased physical activity to 150 min per week.	DV5: sitting standing repeated x 2 30sec between intervals.	ranked test were also used. Correlation between number of sessions attended and continuous demographics were calculated with Spearman correlation coefficient r since the # of attended sessions was not normally distributed. McNemar test was used for categorical variables (lifestyle) between pre-intervention and post intervention. Analysis carried out		AP: S: Indication that paired diet and activity produce statistically significant results when delivered by diabetes educator.

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			AR: 13, no show for post assessment.			with SAS statistical package.		
Block, G., et al. (2015). Diabetes prevention and weight loss with fully automated behavioral intervention by email, web, and mobile phone: A randomized controlled trial among persons with prediabetes Country: USA Bias: Some authors are owners of Turnaround health and Nutrition Quest.	Trans-theoretical model	Design: Randomized, wait list (usual care) trial among patients with clinical evidence of prediabetes. RCT Purpose: Evaluate the effectiveness of a fully automated algorithm-driven behavioral intervention for diabetes prevention, Alive - PD, delivered via the Web, Internet, mobile phone, automated phone calls.	N = 339 N - Alive PD intervention = 163 N - CG = 176 Attrition 15% Total N completed study: 268 Mean Age: 55 Mean BMI: 31.2 Male: 68.7% Mean FBG: 109 w/ SD 8.4 Mean HbA1C: 5.6% SD 0.3.	IV1 – Automated algorithm driven behavioral intervention diabetes program via Web, Internet, mobile phone, and automated phone calls developed by diabetes educators, dieticians, and endocrinologists. IV2: CG Primary DV: HbA1C and FBG. Secondary DV: Body weight, BMI, waist circumference, TG, HDL,	Primary DV: Lab values HbA1C and FBG with local laboratory. Secondary DV: Waist measurements midpoint between lower rib margin and iliac crest. Wt. and BMI calculated scale no shoes. TG and HDL local laboratory.	Intention to treat analyses of change in HbA1C weight and FBG prespecified. Chi Square tests for categorical variables and t test for continuous variables. Mean between group treatments in outcome were evaluated by	Significant decrease in HbA1c and fasting glucose observed at 3 and 6-month interval (p: < .001) Wt. reduction, BMI, waist circumference, and TG/HDL ratios were all significantly greater in intervention group than control	S: Fully automated systems appear to further assist in reduction of primary DV and secondary DV. S: Decreased cost to practice to provide and decreased staffing needs. WN: Inclusion of human interaction likely holds increased response vs total automation such as Alive PD program. WN: Access to technology needed for involvement in automated program i/e Cost to patient. WN: Bias noted developers of program participated in study design.

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the developers of Alive PD.			IV: Alive PD DV: HbA1c, FBG, body wt., BMI, WC, TG, HDL, Inclusion criteria: Age: 30-69. BMI: at least 27 (>25 if Asian). English speaking. Not taking diabetes medication. Access to internet and email. HbA1c 5.7-6.4% Exclusion criteria: Those not meeting the above criteria AR: 3M: 11.9%. 6M: 14.9% Total N: 47			intention to treat analysis using linear regression.	group. (p: <.001)	AP: Integration of automated technology paired with person to person diabetes training has potential to effectively augment prediabetes from advancing to type 2 diabetes.

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<p>Xiao, H., et al. (2015). Wellness coaching for people with prediabetes: a randomized encouragement trial to evaluate outreach method at Kaiser Permanente, Northern California 2013.</p> <p>Country: USA</p> <p>Bias: Outreach low intensity. Only KPNC participants.</p>	Health belief model	<p>Design: Randomized Controlled Trial with outcome data collected prospectively</p> <p>Purpose: Assess relative success of 3 outreach methods (secured email, telephone message, and mailed letter) on the use of wellness coaching by people with prediabetes.</p>	<p>N = 14,584 PreDM N – M: 8,712 (60%) N – W: 5,872 (40%)</p> <p>Mean Age: 59 43% - obese 35% - overweight 57% - Caucasian</p> <p>Setting: KPNC</p> <p>Inclusion criteria: Active KPNC member, Age: 18-80. Lived in California. English speaking. FBG: 110-125 w/in 6 M of study start date.</p> <p>Exclusion criteria: Previous participation in KPNC WCC study. Any following conditions:</p>	<p>IV1 - SE IV2 - IVR IV3 - TM IV4 - ML IV5 -UC</p> <p>DV1 – WCC appointment made w/in 6wks of IV 1-5.</p> <p>DV2: no WCC appointment made.</p>	<p>DV1: WCC appointments made post IV 1-5.</p> <p>DV2: WCC appointments made post UC.</p>	<p>X squared tests to compare categorical variables.</p> <p>Multivariable logistic regression was used to analyze the independent predictors of the outcome and calculate odds ratios and 95% confidence interval for assessing association between the outcome and independent variables.</p> <p>Significance set at <.05 level.</p> <p>Analysis using SAS version 9.1.3.</p>	<p>All uptake rates of scheduling WCC were higher in all intervention arms over UC.</p> <p>Secured Email had the highest rate of success in WCC appointments made.</p>	<p>S: Any outreach intervention to complete WCC had higher WCC outcome than UC with no intervention.</p> <p>S: Email seen as most likely intervention to succeed in WCC appointment to be made.</p> <p>WN: Low intensity interventions.</p> <p>WN: Cost not outlined in regards to IV1-5.</p> <p>WN: limited population studied only KPNC patients.</p> <p>AP: S: Study assists in information of how to attain higher in involvement in WCC and education for prediabetics as a whole.</p>

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			Acute MI w/in prev. year. Corticoid use w/in one year, pregnancy, DM, dementia, or cancer. Excluded r/t possible elevation glucose unrelated to prediabetes. AR: not measured r/t encouragement trial.					
Parker, A., et al. (2014). The effect of medical nutrition therapy by a registered dietician nutritionist in patients with prediabetes participating in a randomized controlled clinical research trial. Country: USA Bias: Short time period. One	Health Belief Model	Design: Prospective, randomized parallel group study. Purpose: The effect of MNT compared with UC on FBG, HbA1C, SL, DRS.	N= 81 N-MNT = 43 N- UC = 38 HbA1C: 5.7%-6.4% Demo: 52.8% Hispanic 27.5% non-Hispanic white Setting: Anaheim, CA r/t ethnic diversity. Inclusion Criteria:	IV1: 30 min MNT IV2 no-MNT DV1 – FBG DV2 – HbA1C DV3 – SL DV4 - DRS	DV11-3 laboratory values. DV4: Screening tool	FRMA of variance. ES of 0.25 and testing at alpha =.05. 95% PTD differences in outcome measurement with SS of 54 patients (27 per group) Independent t test, Fisher exact two sided test	Statistical significance seen in HbA1C and DRS with IV1. Significance seen in DV1-4 in comparison to IV1 vs IV2 but not to the level of statistical significance sent at p<.001.	S: RCT S: Comparison of comparison to MNT group S: Follows the ADA standards of Medical Care in Diabetes. WN: 12 weeks considered relatively short intervention time. WN: Conducted at only one clinical site. WN: Possible patient bias in regards to IV1 group. AP: Compares UC to MNT and indicates statistical significance

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clinical site. Health improvement vs lab values bias.			Age: 18 or older. No Hx of DM 2 treatment. FBG: >100 ->126. HbA1C: 5.7-6.4%. BMI: 25% or higher. Not having RA (30min 5 x week) Exclusion criteria: HX of DM 2. Use of DM meds. Concomitant meds which interfere w/ glucose: corticoid steroids, wt. loss meds, etc. Breast feeding/pregnancy, refusal of informed consent. Hospitalized last 6 M r/t : HD,CVA, TIA. Mental incapacity, unwillingness, or language barrier. AR: 39			and Pearson x squared test used for analysis of demographic characteristic Conducted with G Power analysis program.		in prevention of prediabetes to type 2 diabetes.
Orozco, L.J., et al. (2008). Exercise or	Trans-theoretical Model	Design: Systematic review based on Cochrane review criteria.	n = 2241 N - diet and exercise: 2509	IV1: Diet only. IV2: Diet and Exercise. IV3: Exercise only.	Primary Measurement:	ITT analysis was performed in all studies	Diet and exercise interventions are able to	S: Cochran Review

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exercise and diet for preventing type 2 diabetes mellitus. Country: 2: USA 1: Italy 1: Finland 1: UK 1: Japan 1: China 1: India Bias: Funnel plot bias		Purpose: To assess the effects of exercise, diet, or exercise and diet for preventing type 2 diabetes mellitus.	N – Diet: 167 N – Exercise only: 178 n, RCT = 8 N range (78-3234) Mean Age: 50.3 y/o Mean BMI: 31.2 Inclusion Criteria: Metabolic syndrome or two components of metabolic syndrome (+) high sensitivity CRP serum values = or > 3. One study was overweight (30% to 100% ideal body weight), nondiabetic, and to have one or two biological parents with diabetes mellitus. In other 6 studies glucose tolerance alterations.	DV: Primary: IDM Secondary: IFG, Anthropometric measures, Lipids, SBP and DBP.	Advancement to Type 2 diabetes. Secondary Measurements : Dev of IFG with baseline to 2hr GTT Anthropometric measurement was defined as BMI. Lipid levels: TC, HDL, LDL, TG through laboratory.	when sufficient data was available. Univariate measurement completed throughout all reviews.	decrease the risk of advancement of IFG patients to type 2 diabetes.	S: Intervention supports the development of diet and activity plan by CDE. WN: 2 studies identified as low risk bias. AP: Diet and exercise demonstrated to be at least as effective as medication in prevention of type 2 diabetes.

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
			<p>Exclusion Criteria: Presence of chronic diseases that could interfere with the participation in the intervention group or to complete follow up, and the use of medications that could interfere with the results. 3 studies did not report exclusion criteria.</p> <p>AR: Variable between studies range 2-38%</p>					

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
<p>Norris, S.L., et al. (2010) Long term non-pharmacological weight loss interventions for adults with prediabetes.</p> <p>Country: Not indicated.</p> <p>Bias: Incomplete # of responders. Crude scoring for diet</p>	<p>Trans-theoretical model</p>	<p>Design: Systematic review based on Cochrane review criteria.</p> <p>Purpose: To assess the effectiveness of dietary, physical activity, and behavioral weight loss, and weight control interventions for adults with prediabetes.</p>	<p>N = 5,168 N RCT = 9</p> <p>F/U intervals averaged: 3.2 years.</p> <p>Mean Age: 51.2 W%: 50% Mean Baseline weight: 82.2kg Mean BMI: 28.7 HbA1C: 5.8%</p> <p>Age: 18 or greater. Prediabetic defined as IFG, abnormal OGTT, or combination of the two.</p> <p>Inclusion criteria: Studies were included if they were published or unpublished randomized controlled trials in any language and examined weight loss or weight control strategies using one or more dietary, physical activity, or</p>	<p>IV1: Diet only. IV2: Exercise only. IV3: Combination diet and exercise behavioral interventions.</p> <p>DV – Primary: weight, BMI, percentage of weight loss from baseline.</p> <p>DV - Secondary: CVD, HbA1C, IFG, FBG, Lipids, BP.</p>	<p>Primary: Weight was measured in kilograms.</p> <p>Secondary: Serum values used from laboratory results.</p>	<p>Funnel plot: exploratory data analysis to assess for possible small sample bias.</p> <p>Statistical pooling: when data available to estimate effect.</p> <p>Subgroup analysis and investigation of heterogeneity when sufficient data permitted.</p> <p>Meta-regression was performed using SAS.</p>	<p>On review of RCTs where wt. loss intervention used dietary, physical activity or combination of both for behavioral intervention produce statistically significant weight loss and thereby reduction in the risk of prediabetics to type 2 diabetes as well as other health related benefits.</p>	<p>S: Cochran Review</p> <p>S: Intervention supports the development of diet and activity plan by CDE.</p> <p>AP: Improvement in weight and reduction of advancement to Type 2 diabetes appear to be attainable goals for individuals with prediabetes.</p>

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
			behavioral interventions, with a follow-up interval of at least 12 months. Exclusion criteria: Pharmacologic therapy, surgery, acupuncture, and hypnosis for the purpose of weight loss. Herbal remedies and dietary supplements. Unintentional weight loss, binge eating, and eating disorders. AR: 4% at 1 year. 43% at 10 years.					

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
<p>Maindall, H. T., et al. (2012). Three-year effects on dietary quality of health education: a randomized controlled trial of people with screen-detected dysglycemia (The ADDITION study, Denmark).</p> <p>Country: Denmark</p> <p>Bias: Incomplete responders in analysis. Loss to follow up. Crude score for dietary measures.</p>	<p>Trans-theoretical model</p>	<p>Design: RCT</p> <p>Purpose: To investigate long term efficacy of a theory-based health education program 'Ready to Act' on dietary quality in people with screen detected dysglycemia.</p> <p>AR: 3-year mark 13% = 65</p>	<p>N PreDM/DM = 509. I N = 322 C N = 187</p> <p>1 yr. N = 467 LTF: I N = 26 LTF: C N = 16</p> <p>3 yr. N = 444 LTF: I N = 16 LTF: C N = 15</p> <p>Inclusion Criteria: Screened as Pre-Diabetic (IGT, IGF) DM2.</p> <p>Exclusion criteria: Unable to take part in ambulatory-based activity. Pregnant Involved in other related intervention study. DM Understand English (written and verbal). Give informed consent.</p> <p>AR:</p>	<p>IV1: HE 'Ready to Act' IV2: UC</p> <p>DV1: HbA1C DV2: BMI DV3: IFG/IGT DV4: DC</p>	<p>Clinical data including diagnosis, duration of diagnosis, HbA1C, BMI measured by primary care provider at start.</p> <p>Sociodemographic data, psychosocial conditions, and health behaviors collected through questionnaires at 1 and 3 yr follow up.</p>	<p>Chi square test for comparison of categorical variables.</p> <p>Nonparametric Mann-Whitney/Student t-test with continuous variables.</p> <p>Multilevel regression analyses w/ repeated measurement for dietary intake.</p> <p>ITT analysis</p> <p>Proc Mixed in SAS</p>	<p>Effect of dietary quality with a theory based health education program as part of stratified intervention program to individuals screened as prediabetics.</p> <p>ITT analysis revealed statistically significant higher net change in dietary quality favoring the intervention groups at 1 and 3 years.</p>	<p>WN: incomplete numbers of responders at evaluation times.</p> <p>WN: dietary habits are difficult to interpret and have risk of patient bias.</p> <p>S: study indicates statistical significance with dietary health education and reduction of advancement to diabetes.</p> <p>S: long period of examination 3 years' study.</p> <p>S: randomized controlled trial.</p> <p>AP: Dietary education supports risk reduction of advancement of diabetes and assists in behavior modification that supports better degree of overall health.</p>

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
			1 yr: 42 3 yr: 31					
Morey, M. C., et al (2012). Enhanced fitness: a randomized controlled trial of the effects of home-based physical activity counseling on glycemic control in older adults with prediabetes. Country: USA Bias:	Trans-theoretical model	Design: Randomized controlled clinical trial Purpose: To determine whether a home based multicomponent physical activity counseling (PAC) intervention is effective in reducing glycemic measures in older outpatients with prediabetes mellitus.	N = 302 PAC N = 180 UC N = 122 Inclusion Criteria: HbA1C<7% FBG: 100-125 OW/BMI: 25-45% Age: 60-89 Exclusion Criteria: Exceeded current PA recommendations. DM	IV1: 12 M home based PAC. IV2: UC with VA weight management program Primary DV1: Glucose level. Secondary DV2: TC DV3: LDL DV4: Strength DV 5: GH DV6: 6min walk time. DV7: WC	Primary measurement: Homeostasis model assessment of insulin resistance. Fasting insulin and glucose levels at base line and 3 and 12 months. Secondary measurement: HbA1C was secondary indicator of	ITT criteria with 3 data points baseline, 3 months, and 12 months. Interpretation of the degree of significance was adjusted to reflect the three outcomes for glycemic indicators using	No significant changes in glucose control between Intervention group and UC group.	S: long term study. S: RCT S: Size WN: Self reporting on many aspects of study. WN: Randomization limitations. AP: Indicates the importance of both diet and activity from credentialed provider as more likely positive effect in glucose control and prevention of prediabetes to type 2 diabetes.

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Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables & Definitions	Measurement	Data Analysis	Findings	Decision for Use in Practice/Application to Practice
Self-reported activities.			NG BMI outside of study range. Primary care outside of VAMC. Medical contraindication. Regular activity. Deceased. Other. AR =40		glucose control	Bonferroni correction.		

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Appendix E

Articles	Cole, et al.	Gopalan, et al.	Kramer, et al.	Block et al.	Xiao, et al.	Parker, et al.	Orozco et al.	Norris, et al.	Maindal, et al.	Morey, et al.
Article specifics:										
Year of Article	2013	2015	2011	2015	2015	2014	2008	2005	2012	2012
Research Design	RCT	Pooled cross-sectional analysis	Non-randomized 1-group prospective pretest posttest study	RCT	RCT	RCT	SR	SR	RCT	RCT
Level of Evidence	II	III	III	II	III	II	I	I	II	II
Sample Size	94	20,686	81	339	14,584	81	2241	5,168	509	302
Mean Baseline: FBG/HbA1C (%)	109±9.5mg/dl	5.9-6.0%	101.9±16.7	109.9±8.4/5.6%	110-114 =7,790 115-119 =2584 120-125 =9007	5.95-5.99%	5.4-6.27%	Inclusion 110-199	6.0-6.1%	5.89-5.91%
Interventions (IV's)										
Individual Activity Education							X			X
Individual Diet Education							X			
Group Diet/Activity Education	X						X	X	X	
Individual Diet/Activity Education			X	X	X	X	X	X	X	
Education on Prediabetes/Type 2 diabetes	X		X	X	X	X	X	X	X	X
Automated Electronic Education		X			X					
Effects of IVs on DVs										
Weight	↓		↓	↓		↓	↓	↓		≈
Body Mass Index				↓		↓	↓	↓		≈
Systolic Blood Pressure			↓				↓	↓		≈
Diastolic Blood Pressure			↓				↓	↓		≈
Fasting Blood Glucose	↓		↓	↓			↓			≈
Physical Activity		↑				↑				≈
Dietary Management		↑				↑			↑	
Weight Management and Physical Activity		↑				↑				≈
Total Cholesterol			↓			↓		↓		≈
HDL				↑						≈
LDL			↓			↓				≈
Triglycerides			↓	↓						≈
Increased Follow Up Care					↑					≈
HbA1C/Risk of advancement to Type 2 Diabetes		↓		↓		↓	↓	↓		≈

Appendix F

Theoretical Foundations of Nursing. (n.d.). Retrieved from Nursing Theories:
<http://nursingtheories.weebly.com/nola-pender.html>

Appendix G

Health promotion model. (2015). Retrieved from Nursing Theory: <http://nursing-theory.org/theories-and-models/pender-health-promotion-model.php>

Appendix H, I



APPROVAL: EXPEDITED REVIEW

Debra Hagler
 CONHI Academic Innovation
 602/496-0802
 DEBRA.HAGLER@asu.edu

Dear Debra Hagler:

On 8/5/2016 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Health Education for Prediabetics
Investigator:	Debra Hagler
IRB ID:	STUDY00004619
Category of review:	(5) Data, documents, records, or specimens
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	<ul style="list-style-type: none"> • Chart review data schedule.pdf, Category: Other (to reflect anything not captured above); • IRB Recruitment Script, Category: Recruitment Materials; • Site approval letter, Category: Consent Form; • IRB Submission Form 8-4-16 .docx, Category: IRB Protocol; • IRB Consent, Category: Consent Form; • HIPAA Consent forms for Patient and Employee, Category: Other (to reflect anything not captured above);

The IRB approved the protocol from 8/5/2016 to 8/4/2017 inclusive. Three weeks before 8/4/2017 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

Appendix J

(Whole 30 Program Rules and American Diabetes Association Activity Recommendations)

Appendix K

IRB Knowledge Assessment Evaluation

1. Which of these foods contain carbohydrates?
 - a. A Yogurt Smoothie*
 - b. A Chicken breast
 - c. A slice of American Cheese*
 - d. An Apple*
 - e. A slice of White Bread*

2. Which of these foods would be considered a Fruit?
 - a. Sweet Potato
 - b. Red Apple*
 - c. Green Peas
 - d. Yellow Corn

3. Which of the below foods would be considered a Vegetable?
 - a. Kale
 - b. Broccoli
 - c. Asparagus
 - d. Black Berry*

4. Which of the below popular drinks contain artificial sweetener?
 - a. Fresh brewed Iced Tea unsweetened
 - b. Diet Coke*
 - c. Crystal Light*
 - d. Skinny Starbuck's Latte*

5. Which of the below foods is considered dairy?
 - a. Greek Yogurt*
 - b. Cow's Milk*
 - c. Almond Milk
 - d. 1/2 and 1/2 creamer*

6. Which of the below foods contains sugar?
 - a. Heinz Ketchup*
 - b. Hidden Valley Ranch Dressing*
 - c. Olive Oil/Balsamic vinegar for dressing
 - d. Sweet Baby Ray's Barbeque Sauce*

7. Which of the below foods contains wheat?
 - a. Spaghetti noodles*
 - b. Organic ~~Triscuit~~ Triscuit*
 - c. Kashi Heart to Heart Honey Toasted Oat Cereal
 - d. English Muffin*

8. What is the minimum recommendation for amount of aerobic exercise per the American Diabetes Association?
- 10 min 5 x week/50 min per week
 - 20 min per day/140 min per week
 - 30 min 5 x week/150 min per week*
 - 40 min per day/ 280 min per week
9. What is the schedule for aerobic exercise recommended by the American Diabetes Association?
- No more than 48 hours between occurrence*
 - 4 days a week
 - No more than 72 hours between occurrence
 - 7 days a week
10. Which of the below are examples of aerobic activity?
- Slow walking
 - Swimming*
 - Dancing*
 - Moderate to heavy gardening*
11. What is the recommendation of strength training/resistance training per the American Diabetes Association?
- 1 x week in addition to aerobic exercise
 - 2 x week in addition to aerobic exercise*
 - 3 x week in addition to aerobic exercise
 - 5x week in addition to aerobic exercise